UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

MARY CASTEEL

Civil Action No. 07-cv-02821

Plaintiff,

V.

COMPLAINT

COMPLAINT

JURY TRIAL DEMAND

Defendant,

Defendant,

Plaintiff, Mary Casteel ("Casteel"), file this civil action against Defendant, Merck & Co., Inc. ("Merck") as follows:

PARTIES

- Mary Casteel is a citizen and resident of the State of Tennessee, residing in Columbia,
 Tennessee.
- 2. At all times herein mentioned, Merck was and is a Delaware corporation, with its principal place of business at One Merck Drive, Post Office Box 100, Whitehouse Station, New Jersey 08889-0100.
 - 3. At all times herein mentioned, Merck did business in the State of New York.

JURISDICTION

4. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00) and Casteel is a citizen of a State which is different from the State where Merck is incorporated and has its principal place of business.

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FACTUAL BACKGROUND

- 5. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.
- 6. Fosamax is the brand name of Alendronate Sodium, which is in a class of prescription drugs called bisphosphonates. Fosamax is administered orally.
- 7. Fosamax was approved by the United States Food and Drug Administration for the treatment and prevention of osteoporosis.
- 8. The product literature prepared by Merck and circulated to physicians for use in prescribing the drug contained no warning and/or an inadequate warning about osteonecrosis of the jaw or other bone structure.
- 9. In January, 2002 or before, Merck received information that bisphosphonates, including Alendronate Sodium, were associated with osteonecrosis of the jaw.
- 10. Merck sent some information to some health care providers regarding a possible risk of osteonecrosis of the jaw with the use of Fosamax in July, 2005.
- 11. Merck has yet to send any information to dentists or oral surgeons regarding the fact that Fosamax can and does cause osteonecrosis of the jaw.
 - 12. Casteel was prescribed and she took Fosamax.
 - As a result of taken Fosamax, Casteel developed osteonecrosis of the jaw. 13.
- 14. As a result of taking Fosamax, Casteel suffered compensable injuries, including but not limited to the following:
 - severe and permanent physical and medical injuries and associated disabilities; a.
 - severe past and future pain and suffering; b.

- c. severe past and future mental anguish;
- d. loss of enjoyment of life;
- e. increased risk of health problems;
- f. past and future dental care and monitoring; and
- g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

- 15. Casteel incorporates by reference the allegations contained in Paragraphs 1 through 14 of the Complaint as if they were set forth herein full.
- 16. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.
- 17. Fosamax as designed, manufactured and sold by Merck was defective in design or formulation in that it was unreasonably dangerous.
- 18. Fosamax as designed, manufactured and sold by Merck was defective in design or formation in that its foreseeable risks exceeded the benefits associated with the design or formulation.
- 19. Fosamax as designed, manufactured and sold by Merck was defective due to inadequate warnings because Merck knew or should have known that the product created a risk of harm to consumers.
- 20. Fosamax as designed, manufactured and sold by Merck was defective due to inadequate testing.

21. As the proximate cause and result of the defective condition of Fosamax as designed, manufactured and sold by Merck, Casteel was injured.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure to Warn]

- 22. Casteel incorporates by reference the allegations contained in Paragraphs 1 through 14 of the Complaint as if they were set forth herein full.
- 23. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.
- 24. Fosamax as designed, manufactured and sold by Merck was not accompanied by proper warnings regarding possible adverse side effects.
- 25. Merck knew or should have known about the possible adverse side effects of Fosamax, including osteonecrosis of the jaw.
- 26. As the proximate cause and result of Merck's failure to properly warn physicians and consumers, Casteel was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

- 27. Casteel incorporates by reference the allegations contained in Paragraphs 1 through 14 of the Complaint as if they were set forth herein full.
- 28. Merck designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax.
- 29. Merck had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax, including a duty to assure that

users, like Casteel, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

- 30. Merck failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax in that Merck knew or should have known that Fosamax created an unreasonable risk of osteonecrosis of the jaw.
- 31. Merck was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Fosamax.
 - 32. As the proximate cause and result of Merck negligence, Casteel was injured.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

- 33. Casteel incorporates by reference the allegations contained in Paragraphs 1 through 14 of the Complaint as if they were set forth herein full.
- 34. Merck expressly warranted, by and through statements made by Merck or its authorized agents, that Fosamax was safe, effective, and fit for its intended use.
- 35. Casteel, and her health care providers, relied on the skill, judgment and representatives of Merck.
- 36. Fosamax did not conform to Merck's express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.
- 37. As the proximate cause and result of Merck's breach of its express warranties, Casteel was injured.

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FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

- 38. Casteel incorporates by reference the allegations contained in Paragraphs 1 through 14 of the Complaint as if they were set forth herein full.
- 39. Merck impliedly warranted to Casteel, and her health care providers, that Fosamax was of merchantable quality and was safe and fit for its intended use.
 - 40. Casteel, and her health care providers, relied on Merck's skill and judgment.
- 41. Fosamax was not of merchantable quality or safe and fir for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.
- 42. As the proximate cause and result of Merck's breach of its implied warranties, Casteel was injured.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Mary Casteel, respectfully prays for relief and judgment against the Defendant, Merck & Co., Inc., as follows:

- compensatory damages in an amount to be determined at trial; a.
- attorneys' fees, expenses and costs of this action; and b.
- c. for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff, Mary Casteel, respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PITTMAN GERMANY ROBERTS & WELSH, L.L.P.

Dated: New York, NY April , 2007